UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

United States of America,

Plaintiff,

v.

(2) Moran Oz;
(3) Babubhai Patel;
(8) Elias Karkalas;
(9) Prabhakara Rao Tumpati;

Defendants.

Crim. No. 13-273 (SRN/JJK)

REPORT AND RECOMMENDATION

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JEFFREY J. KEYES, United States Magistrate Judge

In this case, the government charges several defendants with conspiring to violate the Food Drug and Cosmetics Act, introducing misbranded drugs into interstate commerce, conspiring to commit mail fraud and wire fraud, committing mail fraud and wire fraud, unlawfully distributing and dispensing controlled substances, conspiring to launder money, and conspiring to distribute a controlled substance. Defendants (2) Moran Oz, (3) Babubhai Patel, (8) Elias Karkalas, and (9) Prabhakara Rao Tumpati have moved to dismiss certain counts in the

Indictment. These motions include Karkalas and Tumpati's motions to dismiss certain counts as void for vagueness (Doc. Nos. 339, 379), Karkalas and Oz's motions to dismiss certain counts for failure to state an offense (Doc. Nos. 340, 377), Tumpati's motion to dismiss (Doc. No. 380), Patel's motion to join (Doc. No. 417), Karkalas's motion to dismiss certain counts for violating due process rights (Doc. No. 353), and Oz's motion to dismiss duplicative counts (Doc. No. 376). The Government also moved to dismiss certain counts, acknowledging that some of the counts in the Indictment are duplicative. (Doc. No. 395.) The Court held a hearing on the motions on December 8, 2015. Elias Karkalas testified on his own behalf to facts relevant to his due-process motion. The Court also received post-hearing briefing relating to several of the motions. Based on the motions and submissions prior to the hearing, the argument and testimony presented at the hearing, and on the post-hearing briefing, the Court now makes the following report and recommendation.[1] *See* 28 U.S.C. § 636; D. Minn. LR 72.1.

I. Karkalas's and Oz's Motions to Dismiss Certain Counts for Failure to State an Offense at Docket Numbers 340 and 377 and Patel's Motion to Join at Docket Number 417

Karkalas, Oz, and Patel move to dismiss the counts of the Indictment which accuse them of violating the Controlled Substance Act ("CSA") by distributing a drug named Fioricet. They contend that as a matter of law the Indictment fails to allege that any criminal offense occurred. (*See* Doc. Nos. 340, 377, 417, 436.) Rule 12 of the Federal Rules of Criminal Procedure provides that a defendant asserting that an indictment fails to state an offence must do so by a pretrial motion, Fed. R. Crim. P. 12(b)(3)(B)(v), as Defendants have done here. In the Eighth Circuit:

[1] This Court has also issued a separate Report and Recommendation addressing motions to suppress certain statements and for severance of the defendants' trials.

> An indictment adequately states an offense if: it contains all of the essential elements of the offense charged, fairly informs the defendant of the charges against which he must defend, and alleges sufficient information to allow a defendant to plead a conviction or acquittal as a bar to a subsequent prosecution. An indictment will ordinarily be held sufficient unless it is so defective that it cannot be said, by any reasonable construction, to charge the offense for which the defendant was convicted.

United States v. Hayes, 574 F.3d 460, 472 (8th Cir. 2009) (quoting *United States v. Sewell*, 513 F.2d 833, 834 (8th Cir. 2008) (quotation marks omitted)). The indictment must allege that the defendant engaged in conduct which "would constitute a violation of the law under which he has been charged." *United States v. Polychron*, 841 F.2d 833, 834 (8th Cir. 1988). Thus, if the conduct alleged in the indictment does not constitute a criminal offense, then the indictment should be dismissed. *United States v. Finn*, 919 F. Supp. 1305, 1339 (D. Minn. 1995) (citing *United States v. Coia*, 719 F.2d 1120, 1123 (11th Cir. 1983)).

The Government has charged Karkalas, Oz, and Patel with violating the CSA by delivering, distributing, or dispensing Fioricet, which the Government asserts is a controlled substance. (*See* Doc. No. 5, Indict., Counts 61–72, ¶¶ 1–6;[2] *id.*, Counts 73–83.) The CSA charges involve several statutory provisions. In relevant part, the CSA provides that "it shall be unlawful for any person knowingly or intentionally to . . . distribute, or dispense . . . a controlled substance," unless that conduct is authorized by the CSA's provisions. 21 U.S.C. § 841(a)(1). Further, under the CSA it is "unlawful for any person to knowingly or intentionally . . . deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by this subchapter." 21 U.S.C. § 841(h)(1)(A). Prohibited conduct involving Internet distribution

[2] Although the Court recommends that Counts 61–72 be dismissed, *see* Part V, *infra*, it does so with the caveat that paragraphs 1 through 6 laid out in the corresponding section of the Indictment should not dismissed in light of their incorporation into other portions of the Indictment.

of controlled substances includes "writing a prescription for a controlled substance for the purpose of delivery, distribution, or dispensation by means of the internet in violation of section 829(e) of [Title 21]." 21 U.S.C. § 841(h)(2)(B).[3] In turn, Section 829(e) requires controlled substances to be distributed to individuals only where there is a valid prescription, which requires a prescription to be "issued for a legitimate medical purpose in the usual course of professional practice by . . . a practitioner who has conducted at least 1 in-person medical evaluation of the patient." 21 U.S.C. §§ 829(e)(1)–(2); *see also id.* § 829(e)(2)(B) (further defining an "in-person medical evaluation" as one that is "conducted with the patient in the physical presence of the practitioner").

In addition, a person violates the CSA's proscription on delivering, distributing, or dispensing controlled substances if he knowingly or intentionally delivers, distributes, or dispenses a controlled substance "by means of the Internet by an online pharmacy that is not validly registered with a modification authorizing such activity as required by section 823(f) of [Title 21.]" 21 U.S.C. § 841(h)(2)(A). The CSA also requires online pharmacies to display certain information on their websites, including:

> (1) The name and address of the pharmacy as it appears on the pharmacy's [DEA] certificate of registration.
>
> (2) The pharmacy's telephone number and email address.
>
> (3) The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted.
>
> (4) A list of States in which the pharmacy is licensed to dispense controlled substances.

[3] Examples of Internet activities that violate the CSA also include "offering to fill a prescription for a controlled substance based solely on a consumer's completion of an online medical questionnaire." 21 U.S.C. § 841(h)(2)(D).

> (5) A certification that the pharmacy is registered under [Part C, Subchapter I, Chapter 13, of Title 21 of the United States Code] to deliver, distribute, or dispense by means of the Internet controlled substances.
>
> (6) The name, address, telephone number, professional degree, and states of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the website or at the request of the owner or operator of the website, or any employee or agent thereof.
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> (7) The following statement, unless revised by the Attorney General by regulation: "This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309.".

21 U.S.C. § 831.

Beyond these statutory provisions, the Indictment also asserts that Karkalas, Oz, and Patel engaged in conduct that ran afoul of regulations promulgated by the Administrator of the Drug Enforcement Agency ("DEA"). (Indict., Counts 61–72 ¶ 4.) By virtue of its administrative rulemaking authority, the DEA promulgated 21 C.F.R. § 1306.04. This regulation requires prescriptions for controlled substances to "be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," and places a duty upon the "prescribing practitioner" to ensure that controlled substances are properly prescribed. *Id.* § 1306.04(a). If a practitioner issues a controlled substance prescription "not in the usual course of professional treatment," such an order "is not a prescription within the meaning and intent of . . . (21 U.S.C. § 829) and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id.*

The foregoing sections of the CSA and the corresponding regulation relating to the legitimacy of controlled substance prescriptions, all of which are identified in the Indictment,

cover the precise unlawful conduct charged to Karkalas, Oz, and Patel. The Indictment asserts that these Defendants (and others):

> knowingly and intentionally delivered, distributed, and dispensed, and aided and abetted the delivery, distribution, and dispensing, of controlled substances [including Fioricet] by means of the Internet: (a) with invalid prescriptions that were issued outside of the usual course of professional practice, and were not for a legitimate medical purpose; (b) by an online pharmacy that was not validly registered with the DEA with a modified registration authorizing such activity; and (c) by an online pharmacy that did not display on its website the information required by 21 U.S.C. § 831[.]

(Indict., Counts 73–83 ¶ 7.) This language in the Indictment tracks the language of the applicable statutes and regulations, and this is a strong basis on which to conclude the Indictment sufficiently states an offense. *See Hamling v. United States*, 418 U.S. 87, 117 (1974) ("It is generally sufficient that an indictment set forth the offense in the words of the statute itself, as long as those words of themselves fully, directly, and expressly, without any uncertainty or ambiguity, set forth all the elements necessary to constitute the offence intended to be punished.") (quotations omitted).

Karkalas, Oz, and Patel's arguments are directed at a single element of the CSA charges. These defendants argue that the charged conduct involving the combination drug Fioricet does not involve a "controlled substance," and therefore does not state a criminal offense. They contend that because Fioricet is not included in any of the DEA's Schedules of controlled substances and is listed on the DEA's Exempt Prescription Products List, Fioricet has been specifically excepted from the criminal provisions of the CSA. (*See* Doc. No. 340 at 2; Doc. No. 377 at 1; Doc. No. 436 at 2–12.) Karkalas, Oz, and Patel's arguments implicate a provision of the CSA that allows the DEA to exempt certain drugs from application of all or any part of the CSA and a regulation by which, according to these defendants, the DEA exempted Fioricet from any of the criminal penalties that could otherwise be imposed for controlled substance violations.

Section 811 of Title 21 of the United States Code authorizes the DEA, through the Attorney General's proper delegation, to "exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part" of Subchapter I of the of the Controlled Substances Act. 21 U.S.C. § 811(g)(3) ("The Attorney General may, by regulation, exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this subchapter if he finds" certain criteria are satisfied). Pursuant to that authority, the DEA enacted a valid regulation providing that certain "compounds, mixtures, or preparations that contain a nonnarcotic controlled substance [including Fioricet[4]]" have "been exempted by the Administrator from the application of sections 302 through 305, 307 through 309, and 1002 through 1004 of the Act (21 U.S.C. 822-825, 827-829, and 952-954) and §§ 1301.13, 1301.22, and §§ 1301.71 through 1301.76 of this chapter for administrative purposes only." 21 C.F.R. § 1308.32 (hereafter "the Exempting Regulation"). The Exempting Regulation also refers to the "Table of Exempted Prescription Products," which is published by the DEA's Office of Diversion Control and includes the drug Fioricet. http://www.deadiversion.usdoj.gov/schedules/ exempt/exempt_rx_list.pdf.

The language of the Exempting Regulations is plain and does not exempt Fioricet from the criminal provisions of the CSA or the applicable regulations in the Indictment.[5] The Exempting Regulation flows from the DEA's properly delegated statutory authority to exempt certain compounds containing a controlled substance from the application of either the entire

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[4] The Exempting Regulation includes a reference to 21 C.F.R. § 1308.13(c), which in turn includes a reference at subparagraph (3) to "[a]ny substance which contains any quantity of a derivative of barbituric acid or any salt thereof," which includes Fioricet.

[5] Because the language of the Exempting Regulation is plain, the Court does not reach the issue whether the DEA's construction of the Exempting Regulation is entitled to deference. (*See* Doc. No. 400, Gov't's Opp'n to Defs.' Mots. to Dismiss for Failure to State an Offense 15–17.)

CSA or any part of the CSA.[6] The Exempting Regulation does the latter; it exempts Fioricet and other drugs from specific and identified provisions of the CSA and the DEA's regulations. Nothing in the Exempting Regulation's text suggests that a compound containing butalbital, a derivative of barbituric acid, is exempted from any criminal provision of the CSA. The Exempting Regulation does not, for example, exempt Fioricet from the application of 21 U.S.C. § 841, which forms the basis for the charges against these Defendants. Nor does the Exempting Regulation include in its text a reference to the DEA's regulations requiring valid prescriptions for controlled substances, including for delivery by means of the Internet, which also underpin the CSA charges in this case. *See* 21 C.F.R. §§ 1306.04, 1306.09. Had the DEA intended to accomplish such an exemption from the CSA's criminal provisions, it certainly could have included language to that effect in the Exempting Regulation. It did not to do so.

In addition, the DEA was explicit about the limited purposes for which the compounds, mixtures, and preparations containing a nonnarcotic controlled substance listed in its text are to be exempt. The Exempting Regulation provides that the covered drugs listed in several regulations and those in the Table of Exempted Prescription Products are exempted from the application of certain provisions of the CSA and other administrative rules "for administrative purposes only." This means that Fioricet is exempted from certain registration, labeling, record-keeping, security, and packaging requirements imposed by the CSA. *See United States v. Riccio*, 43 F. Supp. 3d 301, 305 (S.D.N.Y. 2014) ("By its own terms [the Exempting Regulation] provides an exemption limited to the registration, labeling, packaging, record-keeping and security requirements delineated in a defined list of U.S.Code provisions."); *United States v.*

[6] Fioricet is a compound that contains butalbital, which is a derivative of barituric acid, which is a Schedule III controlled substance. 21 U.S.C. § 812, Schedule III, (b)(1).

Williams, No. Cr-10-216-HE, 2011 WL 4104654, at *1 (W.D. Okla. Sept. 14, 2011) (rejecting defendants' arguments that, based on the Exempting Regulation, Fioricet was not a controlled substance). No reasonable construction of this "administrative purposes only" language can transform this limited exemption in the Exempting Regulation into an exemption from the criminal provisions and penalties laid out in provisions of the CSA that are absent from the Exempting Regulation's text.

All of Defendants' arguments to the contrary ignore or distort the plain language of the Exempting Regulation. For example, Oz contends that by including Fioricet on the Exempt Prescription Products List, the Attorney General "create[d] the exception referenced in [21 U.S.C.] § 812. . . ." (Doc. No. 436 at 3.) Following from this premise, he asserts that "[t]here is no language in [the Exempting Regulation] that provides that the *only* statutory and regulatory provisions from which exempted products are exempt are those listed in the regulation." (Doc. No. 436 at 4.) This argument is based on a flawed reading of both the relevant CSA provisions and the Exempting Regulation itself. Under 21 U.S.C. § 811(g)(3), when the Attorney General determines that a compound, mixture, or preparation qualifies for exception from all or any part of the CSA, the Attorney General may exempt that drug "by regulation." Pursuant to the Attorney General's authority to create an exemption under this statute, the Administrator of the DEA promulgated the Exempting Regulation. The Exempting Regulation exempts certain compounds, mixtures, and preparations containing nonnarcotic controlled substances listed in five administrative rules and those that are on the Table of Exempted Prescription Products from the application of ten sections of the CSA and eight sections of the DEA's implementing regulations. Thus, contrary to Oz's argument, the inclusion of Fioricet on the Exempt Prescription Products List did not create a broader exemption from the operation of the CSA. It

is the Exempting Regulation that sets the boundaries of the executive branch's exercise of statutory authority for an exemption, and the inclusion of Fioricet on the Table of Exempted Prescription Products makes it subject to the limited exceptions laid out in the formal administrative rule.

Oz further argues that his reading of the Exempting Regulation is buttressed by the Exempting Regulation's second sentence. (Doc. No. 436 at 4–5.) The second sentence of the Exempting Regulation provides that "[a]n exception to the above is that those products containing butalbital shall not be exempt from the requirement of 21 U.S.C. 952-954 concerning importation, exportation, transshipment and in-transit shipment of controlled substances." 21 C.F.R. § 1308.32. Oz asserts that since violations of Sections 952–54 carry with them criminal penalties, *see* 21 U.S.C. § 960 (setting forth the punishments for violations of, inter alia, Sections 952–953), "[i]f § 1308.32 applies only to non-criminal, administrative matters, there would be no reason explicitly to include exempted prescription products containing butalbital within the ambit of §§ 952-954." (Doc. No. 436 at 4–5.) This argument also misconstrues the language and effect of the second sentence in the Exempting Regulation. To reiterate, the Exempting Regulation provides that certain compounds, mixtures, and preparations containing nonnarcotic controlled substances (including those that contain butalbital) are exempt from the application of several identified provisions of the CSA for administrative purposes only. The second sentence then carves out a further limitation on this exemption. Pursuant to that second sentence, among the nonnarcotic-controlled-substance-containing drugs to which the Exempting Regulation applies, those containing the controlled substance butalbital "shall not be exempt from the requirement of 21 U.S.C. 952-954 concerning importation, exportation, transshipment and in-transit shipment of controlled substances." 21 C.F.R. § 1308.32. Thus, the DEA created a

regulation that in its first sentence excepts certain drugs from the application of sections 952–954 for administrative purposes only, and in its second sentence provides that such an exception for administrative purposes from sections 952–954[7] does not apply to any product containing butalbital.[8]

For these reasons, the Court concludes that the Indictment adequately states an offense against Defendants Karkalas, Oz, and Patel by alleging that they engaged in conduct that violated the CSA. Their motions to dismiss (Doc. Nos. 340, 377, 417) should be denied.

II. Karkalas's and Tumpati's Motions to Dismiss Certain Counts as Void for Vagueness at Docket Numbers 339 and 379

Defendants Karkalas and Tumpati both seek to dismiss several counts of the indictment on grounds that the government has charged them with an offense that is void for vagueness. (Doc. No. 339, Karkalas's Void for Vagueness Mot.; Doc. No. 379, Tumpati's Void for Vagueness Mot.) The Counts that Karkalas seeks to have dismissed for unconstitutional vagueness charge him with so-called "misbranding" offenses in violation of the Food Drug and Cosmetics Act ("FDCA"), 21 U.S.C. § 331 and 18 U.S.C. § 371 (Indict., Counts 2-3, 8-9, 15-16, 20-21, and 23), and violations of the CSA, 21 U.S.C. § 841 (*id.*, Counts 61-62, 68-69, 71-73, 80,

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[7] There are a number of administrative requirements applicable to the importation, 21 C.F.R. §§ 1312.11–1312.19, exportation, 21 C.F.R. §§ 1312.21–1312. 30, and transshipment and in-transit shipment, 21 C.F.R. §§ 1312.31–1312.32, of controlled substances. In other words, the effect of the second sentence of the Exempting Regulation is that compounds, mixtures, and preparations containing butalbital are still subject to the administrative requirements laid out in these regulations even though other compounds, mixtures, and preparations that contain a different nonnarcotic controlled substance remain exempt.

[8] As the Government points out (Doc. No. 442 at 4–5 (explaining the history of the second sentence's addition to the Exempting Regulation)), the second sentence of the Exempting Regulation was added in response to a decision by the Commission on Narcotic Drugs in 1991 to "terminate the exemption by the Government of the United States of America of the preparations containing butalbital as found in [the Exempting Regulation,]" Exempted Prescription Products, 57 Fed. Reg. 23301-01 (June 3, 1992).

and 82-83). The government also charged Karkalas and Tumpati with a conspiracy to commit a violation of the FDCA by "misbranding" drugs (*id.*, Count 1),[9] and Karkalas and Tumpati each seek to have this Count dismissed as well (*see* Doc. No. 339 at 1 (listing Count 1 among the challenged counts); Doc. No. 379 at 1 (same)). The Government opposes the motion, arguing that the statutes defining the charged FDCA and CSA offenses are not so vague that an ordinary person cannot understand what conduct is prohibited. (*See* Doc. No. 399, *passim*.)

"The Fifth Amendment provides that '[n]o person shall . . . be deprived of life, liberty, or property, without due process of law." *Johnson v. United States*, ___ U.S. ___, 135 S. Ct. 2551, 2557 (2015). "[T]he government violates this guarantee by taking away someone's life, liberty, or property under a criminal law so vague that it fails to give ordinary people fair notice of the conduct it punishes, or so standardless that it invites arbitrary enforcement." *Johnson*, 135 S. Ct. at 2557; *Connally v. General Constr. Co.*, 269 U.S. 385, 391 (1926) ("[A] statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law."); *United States v. Washam*, 312 F.3d 926, 929 (8th Cir. 2002) ("'[L]aws [must]

[9] In Count 24, which Tumpati argues should be dismissed (Doc. No. 379 at 1 (discussing Count 24)), the government charged Tumpati with a mail and wire fraud offense. (Indict., Count 24.) But, as the Government points out (Doc. No. 399 at 1 n.2), Tumpati does not explain in his vagueness motion why the mail and wire fraud allegations are unconstitutionally vague. As best this Court can tell, Tumpati included the charges in Count 24 in his motion to dismiss because the charge incorporates several paragraphs from Count 1, which charges Tumpati with conspiring to violate the FDCA by distributing or dispensing misbranded drugs. Because this Court concludes, as further described in this section of this Report and Recommendation, that the misbranding charges included in the Indictment are not unconstitutionally vague, to the extent Tumpati relies on his vagueness arguments as to Count 1 to support dismissal of the mail and wire fraud charges laid out against him in Count 24, his motion should be denied. Tumpati's motion should also be denied to the extent that it seeks dismissal of any charges under the CSA because the Government did not charge Tumpati with any offenses violating the CSA. Therefore, in the discussion below addressing the alleged vagueness of the charges under the CSA, the Court addresses only Karkalas's motion.

give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly. Vague laws may trap the innocent by not providing fair warning.'") (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972)) (alterations in *Warsham*). Courts evaluating void-for-vagueness challenges apply "[t]he strong presumptive validity that attaches to an Act of Congress," and those "statutes are not automatically invalidated as vague simply because difficulty is found in determining whether certain marginal offenses fall within their language." *United States v. Nat'l Dairy Prods. Corp.*, 372 U.S. 29, 32 (1963).

"'[V]agueness challenges to a statute which do not involve First Amendment freedoms must be examined in light of the facts of the case at hand.'" *Warsham*, 312 F.3d at 929 (quoting *United States v. Mazurie*, 419 U.S. 544, 550 (1975)). "In determining whether a statute is unconstitutionally vague on the facts at hand, [courts in the Eighth Circuit] apply a two-part test." *Id.* "First, the statute must provide adequate notice of the proscribed conduct." *Id.* "Second, the statute must not lend itself to arbitrary enforcement." *Id.*

A. Controlled Substances Act

In Counts 61–62, 68–69, 71–73, 79–80, and 82–83, the Government charges Karkalas with unlawfully delivering, distributing, or dispensing a controlled substance, Fioricet, by writing prescriptions for individuals based solely on their responses to an online questionnaire filled out on the Internet. (Indict. 34–37, Counts 61-72 ¶¶ 5–7; *id.* at 38–41, Counts 73-83 ¶¶ 1–6.) Among the controlled substances covered by the CSA is "[a]ny substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid." 21 U.S.C. § 812, Schedule III, Part (b)(1). Fioricet contains Butalbital, which is a derivative of barbituric acid. *See id.* The CSA provides that it is "unlawful for any person to knowingly or intentionally . . . deliver, distribute, or dispense a controlled substance by means of the Internet,

except as authorized by this subchapter" 21 U.S.C. § 841(h)(1)(A).[10] The CSA further explains that an example of such prohibited conduct includes "offering to fill a prescription for a controlled substance based solely on a consumer's completion of an online medical questionnaire[.]" *Id.* § 841(h)(2)(D).

Karkalas argues that "the Counts charging distribution or dispensing of Fioricet, pursuant to 21 U.S.C. § 841, must be dismissed for the same reason that the law is so vague as to fail to provide fair notice of the conduct prohibited." (Doc. No. 339 at 5.) Karkalas contends that because "Fioricet is not included in any of the referenced schedules . . . and is listed instead on the list published by the Drug Enforcement Administration ["DEA"] of substances that have been exempted from controlled substance scheduling . . . [o]rdinary persons . . . have no fair notice that the possession, dispensing, and distribution of Fioricet are prohibited acts under § 841[.]" (Doc. No. 339 at 5–6; Doc. No. 379 at 5–6.)

As discussed above, CSA allows the Attorney General to "exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part" of Subchapter I of the of the Controlled Substances Act. 21 U.S.C. § 811(g)(3) ("The Attorney General may, by regulation, exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this subchapter if he finds" certain criteria are satisfied). The Exempting Regulation, issued by the DEA pursuant to its rulemaking authority delegated by the Attorney General, provides that certain drugs, including Fioricet, have

[10] The Indictment also charges the defendants with violations of 21 U.S.C. § 841(a)(1), which provides that "it shall be unlawful for any person knowingly or intentionally. . . to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance." In addition, the Indictment references a sentencing provision of the CSA for violations of § 841(a)(1) that involve Schedule III controlled substances. 21 U.S.C. § 841(b)(1)(E). The discussion in Part I of this Report and Recommendation addressing the motions to dismiss for failure to state an offense discusses the CSA charges in more detail.

"been exempted by the Administrator from the application of sections 302 through 305, 307 through 309, and 1002 through 1004 of the Act (21 U.S.C. 822-825, 827-829, and 952-954) and §§ 1301.13, 1301.22, and §§ 1301.71 through 1301.76 of this chapter for administrative purposes only." 28 C.F.R. § 1308.32. Further, the DEA also publishes an "Exempt Prescription Products List," which includes the drug Fioricet. http://www.deadiversion.usdoj.gov/schedules/exempt/exempt_rx_list.pdf.

There is nothing unconstitutionally vague about the provisions of the CSA that prohibit the very conduct Karkalas is charged with in the Indictment,[11] and nothing in either the Exempting Regulation or the Exempt Prescription Products List renders these charges unconstitutionally vague. The Exempting Regulation exempts Fioricet from the requirements of limited portions of the CSA and does so "for administrative purposes only." It does not exempt Fioricet from all of the provisions of the CSA, though the CSA gives the DEA the power to do so. *See* 21 U.S.C. § 811(g)(3) (authorizing the Attorney General to exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this subchapter"). The Exempting Regulation also does not exempt Fioricet from the specific criminal provisions Karkalas is charged with violating. By the Exempting Regulation's plain terms, the DEA chose not to exempt Fioricet from the CSA's prohibition on distributing or dispensing controlled substances, 21 U.S.C. § 841(a)(1); doing so by means of an Internet pharmacy based solely on a consumer's completion of an online questionnaire, 21 U.S.C. §§ 841(h)(1)(A) and 841(h)(2)(D); or from the penalties associated with such prohibited conduct

[11] Sections 841(a)(1), 841(b)(1)(E) and 841(h) of Title 21 of the United States Code plainly and unambiguously cover the acts charged to Karkalas, namely prohibiting a person from distributing or dispensing a controlled substance in a manner other than that allowed by the CSA. Karkalas does not argue otherwise.

when a Schedule III controlled substance is involved, 21 U.S.C. § 841(b)(1)(E). Finally, by placing Fioricet on the Exempt Prescription Products List, the DEA did not somehow amend the plain and unambiguous language of the Exempting Regulation. Nor did the DEA's placement of Fioricet on the Exempt Prescription Products List exempt from the application of the CSA as a whole or from the criminal provisions in the CSA that Karkalas is charged with violating. A person of ordinary intelligence would not read the Exempting Regulation and the Exempt Prescription Products List together and conclude that the exemption for Fioricet from the operation of the listed statutory and regulatory provisions for "administrative purposes only" somehow further exempts Fioricet from unlisted provisions of the CSA that impose criminal penalties.

Other courts have rejected nearly identical vagueness challenges in cases involving alleged violations of the CSA by delivering, distributing, or dispensing Fioricet. In *United States v. Riccio*, 43 F. Supp. 3d 301 (S.D.N.Y. 2014), the Government charged several defendants with violations of the CSA in an indictment alleging that the defendants participated in an internet pharmacy scheme to distribute drugs to customers who visited various prescription websites. *Id.* at 303. One defendant moved to dismiss the CSA charges against him, which specifically alleged that he violated the prohibition on dispensing the controlled substance Fioricet by offering to fill prescriptions for it based only on the customer's completion of an online medical questionnaire. *Id.* at 304. The defendant argued that charged offense was unconstitutionally vague because the statute did not provide fair warning that dispensing Fioricet via prescription website was prohibited conduct. *See id.* at 306–07. The Court rejected this argument, concluding: (1) that the defendant (a trained pharmacist) was expected to be familiar with the relevant laws because of the highly regulated nature of the prescription drug industry; (2) that

because the CSA includes a specific intent requirement, any potential unconstitutional vagueness was properly mitigated; and (3) that prior judicial opinions clarifying the applicability of the CSA to the scheme alleged in the indictment provided the "clarity necessary for fair warning" as required by the Due Process clause. *Id.* at 307; *see also United States v. Williams*, No. Cr-10-216-HE, 2011 WL 4104654, at *4 (W.D. Okla. Sept. 14, 2011) (finding that it was "unnecessary to invalidate the criminal provisions" under the CSA in a case alleging that the defendant distributed Fioricet via an online pharmacy operated without a license because "[t]he specific intent requirement for the crimes charged saves the statutes from potential unconstitutionality"). These same reasons justify denying the vagueness motions directed at the CSA charges here.

The defendants' arguments that the CSA charges are unconstitutionally vague are unpersuasive. The defendants have failed to show that the Exempting Regulation and the inclusion of Fioricet in the Exempt Prescription Products List render any portion of the Controlled Substances Act unconstitutionally vague.[12] Accordingly, for all the foregoing reasons, Karkalas's and Tumpati's motions to dismiss any charges under the CSA as unconstitutionally vague should be denied.

[12] In his Motion to Dismiss Counts 61-83, Defendant Moran Oz contends that "because the statute and regulations fail to provide fair warning to the public that a medication containing a controlled substance that has been listed on the DEA Exempt Prescription Products List is nonetheless subject to the prohibitions against the distribution of a controlled substance, the statute is void for vagueness as applied to a prosecution for distribution of Fioricet." (Doc. No. 377 at 1–2.) Oz further argues, in a post-hearing memorandum, that a person of common intelligence making his way through the applicable laws and regulations could not "unravel [the] Gordian knot [created by the CSA and the DEA's regulations concerning] Fioricet," and asserts that after reading that Fioricet is exempt for administrative purposes only, such a person of common intelligence would conclude that he could not be prosecuted for violating the CSA because Fioricet is not listed in any of the DEA schedules and is on the DEA's Exempt Prescription Products List. (Doc. No. 436 at 16.) This argument fails for the same reasons set forth below on which the Court recommends denying Karkalas's void-for-vagueness motion. Oz's motion to dismiss (Doc. No. 377) should also be denied to the extent it raises vagueness issues.

B. Misbranding under the FDCA

Karkalas and Tumpati also argue that the "misbranding" offenses alleged in the Indictment are unconstitutionally vague because "[a]n ordinary person . . . could not possibly have foreseen that the writing of a prescription for a medication by a physician could somehow amount to a 'misbranding' of the drug itself[.]" (Doc. No. 339 at 2; Doc. No. 379 at 2.)[13] The FDCA prohibits the introduction or delivery for introduction into interstate commerce, or the causing of such introduction or delivery, of any drug that is "misbranded." 21 U.S.C. § 331(a). A person who violates this prohibition on introducing or delivering misbranded drugs in with intent to defraud or mislead shall be imprisoned for not more than three years. 21 U.S.C. § 333(a)(2). As noted above, the government charged Karkalas and Tumpati with a conspiracy to commit a violation of the FDCA by violating these misbranding provisions. (Indict., Count 1.)

The FDCA defines the term "misbranded." In relevant part,[14] the FDCA provides the following:

> (1) A drug intended for use by man which—
>
> > (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

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[13] Karkalas and Tumpati have filed substantially identical motions and, for ease of reference, in the remainder of this section of the Report and Recommendation, the Court will cite only to Karkalas' motion.

[14] The Indictment specifically references this statutory explication of circumstances in which a drug is deemed misbranded. (*See* Indict., Count 1 ¶¶ 3–6, 8 (citing 21 U.S.C. § 353(b)(1)); *id.*, Count 2–23 ¶ 2 (same).) The Indictment alleges that Karkalas and Tumpati both conspired to introduce (Count 1), and that Karkalas did introduce (Counts 2-3, 8-9, 15-16, 20-21, and 23), misbranded drugs into interstate commerce when they signed or authorized sham prescriptions for drugs that required a prescription under federal law and in circumstances where no bona-fide doctor-patient relationship existed.

> (B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;
>
> shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

21 U.S.C. § 353(b)(1)(A)–(B). This statute plainly requires certain potentially harmful drugs to be dispensed to patients only under the supervision of a licensed practitioner and only where that practitioner provides a prescription for such a drug. *Id.* A practitioner provides the required "prescription" in compliance with this statute only when a bona fide physician-patient relationship exists between the practitioner, who gives the order for use of a drug, and the patient for whom the order is prepared. *United States v. Smith*, 573 F.3d 639, 650–53 (8th Cir. 2009) (concluding that 21 U.S.C. § 353(b)(1) requires certain drugs to be dispensed only by a "valid prescription," and that "a valid prescription requires a bona fide physician-patient relationship").[15] Thus, the FDCA makes it a crime for a person to introduce or deliver, or cause to be introduced or delivered, a drug that is "misbranded" because the drug was administered

[15] In *Smith*, the Eighth Circuit relied on several other cases to reach its conclusion that 21 U.S.C. § 353(b)(1) requires any prescription issued to be a valid one, including: *United States v. Nazir*, 211 F. Supp. 2d 1372, 1374–78 (S.D. Fla. 2002) (explaining that the use of "prescription" in 21 U.S.C. § 353(b)(1) requires a bona fide doctor-patient relationship, and where a practitioner writes a "phony" prescription without such a relationship, the practitioner has dispensed a drug contrary to the statute's provisions and such a drug is misbranded); and *Brown v. United States*, 250 F.2d 745, 746–47 (5th Cir. 1958) ("[For charges that a defendant violated 21 U.S.C. § 353(b)(1)] [t]he [jury's] inquiry whether there was a bona fide relationship of patient and doctor bears on the question whether there had ever been a 'prescription' for the [purchaser of the drug].").

without a valid prescription. *See* 21 U.S.C. § 331(a); 21 U.S.C. § 333(a) (providing penalties for violations of 21 U.S.C. § 331).

Karkalas and Tumpati argue that when read together these statutory sections are collectively unconstitutionally vague because an ordinary person, considering the ordinary meaning of "misbranding," would not "conclude that 'misbranding' includes 'dispensing' without a prescription, [and] still would have not statutory guidance to conclude that merely writing a prescription (whether 'valid' or not) somehow constitutes 'dispensing.'" (Doc. No. 339 at 3–4.) The Court disagrees. The misbranding statutes provide a "person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly." *Washam*, 312 F.3d at 929. Section 331(a) plainly prohibits a person from introducing or delivering, or causing the introduction or delivery into interstate commerce, of any drug that is "misbranded." The FDCA does not leave a person guessing as to what it means for a drug to be "misbranded." A plain reading of Section 353(b)(1) shows that certain potentially toxic or harmful drugs must be dispensed with a prescription or else they are deemed "misbranded." And because dispensing such a drug with a prescription requires there to be a bona fide doctor-patient relationship, where a person writes a prescription for such a drug for another in the absence of a bona fide doctor-patient relationship, he has dispensed that drug contrary to the provisions of Section 353(b)(1), thereby rendering it "misbranded." Thus, these statues provide reasonable notice to an ordinary person that he is prohibited from causing the introduction in interstate commerce of a potentially harmful drug that is deemed "misbranded" because he wrote a sham prescription for the drug, thereby dispensing it contrary to the FDCA.

Karkalas and Tumpati appear to contend that even if "dispensing" a drug might include the acts of distributing, shipping, or selling that drug to online customers, thereby rendering it

misbranded under Section 353(b)(1), a person of ordinary intelligence reading that statute would not know that he had "dispensed" a drug merely by writing a prescription. (*See* Doc. No. 339 at 5 ("Nothing in this Indictment, however, or in any of the very voluminous discovery, accuses Defendant Karkalos of 'selling' or 'dispensing' drugs.").) This argument is unpersuasive. First, the Indictment charges Karkalas and Tumpati with violating the FDCA by causing, or conspiring to cause, misbranded drugs to be introduced in interstate commerce. The Indictment further alleges that as part of this conspiracy Tumpati and Karkalas both authorized sham prescriptions for drugs that were required to be administered under the supervision of a physician (Doc. No. 5 ¶¶ 27–28), and those drugs were ultimately distributed to an undercover investigator in Minnesota (*id.* ¶ 57). Thus, Karkalas and Tumpati, by virtue of writing the prescriptions in the absence of a bona fide doctor-patient relationship as part of this alleged conspiracy, engaged in conduct that rendered the prescription drugs misbranded.

Moreover, Karkalas and Tumpati's argument relies upon an incomplete reading of the term "dispense" as it is used in Section 353(b)(1). As noted above, under that provision, "[t]he act of dispensing a drug contrary to the provisions in this paragraph [including requiring valid prescriptions] shall be deemed to be an act which results in the drug being misbranded while held for sale." 21 U.S.C. § 353(b)(1). The common meaning of "dispense" includes not only the distribution, sale, or shipment of an object, but also includes "to put up (a prescription or medication)," *Dispense*, Webster's Third New International Dictionary 653 (1993), or "to portion out," *Dispense*, The Merriam-Webster Dictionary 207 (New Ed. 2004). The act of writing a prescription for a drug portions out that drug or puts up the medication for a patient's use. Writing a prescription for a drug thus falls within these common uses of the term "dispense." Because it is contrary to the requirements of Section 353(b)(1) to "dispense" a

covered medication by writing a sham prescription for that medication where there is no bona fide doctor-patient relationship, Defendants' alleged conduct would result in that medication being deemed misbranded. As a result, by writing such a sham prescription so that misbranded drugs would be distributed to the undercover agents and customers as alleged in the Indictment, Defendants Karkalas and Tumpati would have caused misbranded drugs to be introduced into interstate commerce. *See* 21 U.S.C. § 331(a). Read together, Sections 331(a) and 353(b)(1) therefore "define the criminal offense with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement." *Kolender v. Lawson*, 461 U.S. 352, 357–58 (1983).

Karkalas and Tumpati also argue that "by the Government's theory of prosecution even mere negligence in the approval of a prescription for a regulated medication might land a doctor in prison under this misbranding theory." (Doc. No. 339 at 5.) Defendants do not explain why negligent approval of a prescription is a possibility under the charging theory involved in this case. Nor does the Indictment make a conviction for negligent conduct a possibility. The conspiracy charge in Count 1 of the Indictment indicates that the named Defendants engaged in the alleged conduct "with the intent to defraud and mislead" and relies on 21 U.S.C. § 333(a)(2), which includes such fraudulent intent language. (Indict., Count 1, ¶ 10.) Similarly, Counts 2 through 23, which include the non-conspiracy FDCA charges against Karkalas, also allege that the named Defendants caused the introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead. (*See id.*, Counts 2–23, ¶ 2 (also referencing 21 U.S.C. § 333(a)(2)).) Thus, with respect to the charged violations of the FDCA, the Defendants cannot be convicted upon a mere showing that they acted negligently in approving a prescription. The government has to show that the Defendants intended to defraud and mislead by their conduct.

Courts have rejected void-for-vagueness challenges to the FDCA's misbranding provisions in other cases involving charges that drugs were dispensed without a valid prescription. *See United States v. Forester*, 346 F.2d 685, 685 (4th Cir. 1965) (per curiam) (finding no error in the district court's conclusion that provisions of the FDCA requiring drugs to be dispensed only upon a doctor's prescription, including 21 U.S.C. § 353(b)(1), were not unconstitutionally vague and uncertain); *see also United States v. Travia*, 180 F. Supp. 2d 115, 1 (D.D.C. 2001) (concluding that misbranding provisions of the FDCA were not unconstitutionally vague as applied to a case charging the defendants with distributing misbranded prescription drugs—nitrus oxide—in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 353(b)(1) and explaining that these provisions "are not so vague or standardless that the ordinary public is left uncertain as to what is prohibited").

Like those courts, this Court concludes that a person of ordinary intelligence can read the relevant statutory provisions forming the basis of the misbranding charges in this Indictment and reasonably understand whether the conduct these defendants are charged with engaging in is prohibited. For all the reasons discussed above, the FDCA misbranding charges are not so standardless that they cannot be understood or lend themselves to arbitrary enforcement.

III. Tumpati's Motion to Dismiss at Docket Number 380

Defendant Tumpati "moves this Court to dismiss the indictment against him." (Doc. No. 380 at 1.) In his motion, Tumpati discusses how he received medical training in India and the United States and became involved with telemedicine and, specifically with RX Limited in 2008 while looking for additional employment opportunities. (*Id.* at 1–2.) Tumpati asserts that he was told that RX Limited did not deal with controlled substances and that it was legal for him to write prescriptions for such medications. (*Id.* at 2.) He worked part-time for RX Limited by

reviewing patient medical questionnaires. (*Id.* at 2–3.) Tumpati made "assessment[s]" based on the patient's medical history and other information provided on the questionnaires. (*Id.* at 4–5.) He received income for his RX Limited work through wire transfers. (*Id.* at 5.) Tumpati states that he stopped working for RX Limited in 2011 when he learned that in his State of residence, Pennsylvania, the Board of Medicine was contemplating changing its rules to begin regulating Fioricet (*id.*), which, although Tumpati does not state as much in his motion, is apparently among the medications that he prescribed as a result of the assessments he made based on the information in the patient questionnaires he reviewed. The Board advised him to cease his work with RX Limited, and he asserts that he followed their advice. (*Id.*)

Tumpati first argues that the Indictment fails to state an offense against him because "the indictment in this case rests on the fact that through the process described [in his motion, he] prescribed Fioricet," but Fioricet is exempt from the relevant portions of the CSA by 21 C.F.R. § 1308.32 and the Exempt Prescription Products List. (Doc. No. 380 at 6.) Tumpati acknowledges that he is charged with a count of conspiracy to violate the FDCA and one count of conspiracy to commit mail fraud and wire fraud. (*Id.* at 1.) He is not charged with violating the CSA. Thus, it is unclear why any alleged exemption from the operation of the CSA would have anything to do with the charges against him under the FDCA. Moreover, as described above in the portion of this Report and Recommendation addressing the motions to dismiss for failure to state an offense under the CSA, *see* Part I, *supra*, Fioricet is not exempted from the application of the criminal provisions of the CSA. This first argument provides no basis to dismiss the FDCA charges against Tumpati.

Second, Tumpati argues that the charges that he conspired to violate the FDCA, which are alleged in Count 1 of the Indictment, should be dismissed because "the indictment only lists

some factors that can be used to determine whether such a relationship exists[,]" and that "the FDCA does not specifically define what a bona fide physician-patient relationship is." (Doc. No. 380 at 8.) The misbranding theory alleged in Count I asserts that the Defendants, including Tumpati, conspired to distribute, deliver, or dispense misbranded drugs by writing prescriptions for medications that can only be dispensed to patients under the supervision of a physician who has had in-person contact with those patients. Because the Government alleges that the Defendants, like Tumpati, wrote prescriptions for potentially harmful drugs without having in-person contact with those patients, they lacked the bona fide doctor-patient relationship required by the FDCA, and thus the drugs would be deemed misbranded. Tumpati provides no support for his apparent assertion that the government cannot adequately charge a physician with a misbranding offense under such a theory unless the Government alleges that none of the other factors relevant to the existence of a bona fide doctor-patient relationship were present.

Further, Tumpati argues that he cannot be prosecuted for prescribing Fioricet because he stopped prescribing before the Pennsylvania Board of Medicine changed its rules to begin regulating Fioricet. (Doc. No. 380 at 8.) Tumpati offers no legal support for this argument. At best, Tumpati's decision to stop prescribing Fioricet through RX Limited when the Pennsylvania State Board of Medicine began considering regulating the drug may be relevant to the jury's consideration of whether the government meets its burden to establish that Tumpati is guilty of the charged conspiracy. But this argument presents no basis for dismissing any portion of the Indictment.

Finally, Tumpati makes no argument at all concerning why the conspiracy to commit mail and wire fraud charge against him in Count 24 of the Indictment should be dismissed. Accordingly, his motion to dismiss Count 24 should be denied.

For all the foregoing reasons, Tumpati's motion to dismiss (Doc. No. 380) should be denied.

IV. Karkalas's Motion to Dismiss Certain Counts for Violating Due Process Rights at Docket Number 353

A. The motion

Defendant Elias Karkalas moves to dismiss counts 61-62, 68-69, 71-73, 79-80, and 82-83 (which charge violations of the CSA) on grounds that allowing the prosecution of those counts to go forward would violate his constitutional right under the Due Process Clause of the Fifth Amendment as interpreted in *Raley v. Ohio*, 360 U.S. 423 (1959). (Doc. No. 353.) Karkalas asserts that he "detrimentally relied on the misleading advice of various governmental actors, including the Drug Enforcement Administration, in believing that the compound Fioricet was not a controlled substance within the meaning of the law," and that "[t]he fundamental fairness inherent in the Due Process Clause forbids the Government from taking advantage of its own deception to the manifest prejudice of [Karkalas]." (*Id.* at 2.) In his written, Karkalas did not identify specific affirmative misconduct by any government official that he reasonably relied on in his alleged distribution and dispensing of Fioricet. Instead, Karkalas asserted that he "anticipate[d] offering further evidence and argument in support of this motion." (*Id.*) Prior to the hearing, the government opposed this motion on grounds that Karkalas (1) "fail[ed] to provide any factual support for his contention that the Government's prosecution is unconstitutional, listing not one statement on which he claims he 'detrimentally relied'"; and (2) "even if Karkalas had attempted to provide factual support for his motion, there is a factual question whether Karkalas relied on government statements about Fioricet and whether any reliance would have been reasonable." (Doc. No. 396 at 2.) Karkalas testified at the December

8, 2015 hearing concerning the facts supporting his motion.[16] His testimony is described in the following section.

B. Facts relevant to the motion

Karkalas began practicing medicine in the Commonwealth of Pennsylvania in the early 1980s and continued doing so until 2012. (Doc. No. 422, Tr. of Dec. 8, 2015 Hr'g ("Hr'g Tr.") 71:5–14.) During that period of practicing medicine, he became familiar with the brand name drug Fioricet. (*Id.* at 71:15–19.) During that time he believed that Fioricet was not a controlled substance. (*Id.* at 71:20–23.)

Karkalas identified several statements of attorneys and other pronouncements on which he based that belief. First, in March 2012, Karkalas states that at a hearing before the Pennsylvania State Board of Medicine, Andrew Demarest, an attorney representing the State, told Karkalas that Fioricet was not a controlled substance. (Hr'g Tr. 71:24–72:15.)

At an unidentified time, Karkalas also consulted with his personal attorney Mark Halpern about whether Fioricet is a controlled substance. Halpern told Karkalas that Fioricet is not a controlled substance. (Hr'g Tr. 72:25–73:7.) Karkalas also communicated with an attorney for the manufacturer of Fioricet who told him that Fioricet was not a controlled substance, based upon a representation by the DEA to the manufacturer to that effect. (*Id.* at 73:9–15; *id.* at 73:19–25.) "Several other attorneys" also told him the same thing. (*Id.* at 73:16–18.)

[16] At the hearing, defense counsel indicated that Karkalas was testifying subject to *Simmons v. United States*, 390 U.S. 377 (1968), which held that "when a defendant testifies in support of a motion to suppress evidence on Fourth Amendment grounds, his testimony may not thereafter be admitted against him at trial on the issue of guild unless he makes no objection." *Id.* at 394. This Court offers no opinion concerning the applicability of *Simmons* in this context as the propriety of admitting any evidence at trial is a matter to be determined by the district court.

Karkalas also learned of on an unidentified provision of a recently passed Pennsylvania statute that classified Fioricet as a controlled substance for purposes of Pennsylvania law. Karkalas recalls that the preamble to that statute includes language to the effect that "the Federal Government never designated Fioricet as a controlled substance . . ." so Pennsylvania's legislature felt it necessary to do so. (Hr'g Tr. 74:1–9.)

Further, Karkalas was unaware of the Pennsylvania State Board of Pharmacy's current position concerning Fioricet, but he knew that its former position had been that Fioricet was not a controlled substance, and he recalled that national pharmacy agencies teach pharmacists that Fioricet is not a controlled substance. (Hr'g Tr. 74:15–21.)

And finally, Karkalas believed that Fioricet was not a controlled substance because the Drug Enforcement Agency included Fioricet in the Exempt Prescription Products List. (Hr'g Tr. 74:22–75:5.)

Karkalas met with representatives of the United States in February 2013 to discuss the matters underlying this criminal case.[17] (Hr'g Tr. 75:14–24.) Karkalas brought several documents with him to that meeting. (*Id.* at 75:25–76:2.) He could not remember specifically whether he brought to that meeting the two federal court orders introduced in evidence at the hearing as Government's Exhibit 6 and Government's Exhibit 7. (*Id.* at 76:10–77:21.) He stated that anything he brought to that meeting was to demonstrate to the federal government representatives with whom he was meeting that his own conduct involving Fioricet was not

[17] Karkalas has brought a motion to suppress statements he made at the meetings he had with the Government on February 20, 2013, May 6, 2013, and December 10, 2013. That motion is the subject of a separate Report and Recommendation that addresses Karkalas's motion to suppress the statements he made at those meetings and other motions for severance of the defendants' trials.

prohibited by the Controlled Substances Act. (*See id.* at 77:22–80:18; *see also id.* at 81:23–83:9.)[18]

C. *Raley* and the entrapment by estoppel defense

As noted above, Karkalas bases his motion on *Raley v. Ohio*, in which the United States Supreme Court overturned the convictions of several defendants who had been charged with contempt for refusing to testify before a state legislative commission regarding their suspected communist or subversive activities. 360 U.S. at 425. Before they refused to testify, the chairperson of that legislative commission told the defendants that they could rely on their state-law privilege against self-incrimination and refuse to testify. *Id.* The chairperson's advice about the defendants' right to refuse to cooperate with the commission was incorrect, and the defendants relied on it to their detriment; the state later charged them with contempt based upon their refusal to answer the commission's questions. *Id.* at 438–39. The United States Supreme Court reversed their convictions, concluding that "[a]fter the Commission, speaking for the State, acted as it did, to sustain the Ohio Supreme Court's judgment [affirming the convictions] would be to sanction an indefensible sort of entrapment by the State—convicting . . . citizen[s] for exercising a privilege which the State had clearly told [them] was available to [them]." *Id.* at 426.

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[18] During the hearing Karkalas testified at length about his adamant belief, formed after conducting his own research into the CSA's regulations and receiving the advice of his counsel, and for other reasons, that Fioricet was not a controlled substance and nothing he was doing was illegal. (*See generally* Hr'g Tr. 82:23–101:6.) Much of this testimony relates to the reasonableness of any conclusion Karkalas reached that what he was doing was permissible. The Court does not recount that testimony in detail because, as described in this section, none of the alleged statements by various government officials and non-government lawyers on which Karkalas relies is legally sufficient to obtain dismissal of the Indictment under *Raley*. In other words, the Court does not need to reach the question whether Karkalas reasonably believed that what he was doing was legal because he fails to satisfy the other elements of the affirmative defense of entrapment by estoppel.

Raley is the precursor to the defense of entrapment by estoppel, *United States v. Austin*, 915 F.2d 363, 366 (8th Cir. 1990), which "applies when an official tells the defendant that certain conduct is legal, and the defendant reasonably relies on the advice and continues or initiates the conduct." *United States v. Benning*, 248 F.3d 772, 775 (8th Cir. 2001); *see also Austin*, 915 F.2d at 366. "To successfully present a defense of entrapment by estoppel, [a defendant] bears the burden of proof to demonstrate that: (1) his reliance on the government's statement was reasonable, and (2) the statement misled him into believing his conduct was legal." *Benning*, 248 F.3d at 775 (citing *Austin*, 915 F.2d at 366). A government official "must be guilty of affirmative misconduct in order for a defendant to put forth a viable defense of entrapment by estoppel." *Id.* (citing *United States v. Bazargan*, 992 F.2d 844, 849 (8th Cir. 1993); *United States v. LaChapelle*, 969 F.2d 632, 637 (8th Cir. 1992)).

D. Analysis

After the December 8, 2015 hearing, Karkalas submitted additional briefing in support of his motion to dismiss based on *Raley*. (Doc. No. 437 at 2–5.) In the discussion below, the Court addresses the arguments raised in that post-hearing submission.

First, although it is unclear whether Karkalas contends that prosecuting him for violations of the CSA would violate his rights to due process under *Raley* based on statements he attributes to his personal attorney, Mark Halpern,[19] to the extent he does base his motion on Halpern's advice, such an argument lacks merit. Karkalas presents no case indicating that dismissal under *Raley* or an entrapment by estoppel defense can be based upon the statement of a non-

[19] Karkalas also testified that he spoke to his personal attorney Robert Levy concerning the applicability of the CSA to Fioricet. (Hr'g Tr. 85:10–13.) The Court's comments regarding Halpern's advice to Karkalas applies with equal force to anything Karkalas may have been told by his personal attorney Robert Levy.

governmental actor. There is no evidence that Halpern, or any other personal attorney identified by Karkalas, made any representation to Karkalas on behalf of the United States Government.[20] To show that charging a person with a crime would violate his constitutional rights under *Raley* and the entrapment by estoppel defense, the statements on which the person relies have to be made by a government official. *Cf. United States v. Hullette*, 525 F.3d 610 (8th Cir. 2008) (noting that several decisions have foreclosed the argument "that a federally licensed firearms dealer is a government official whose representation give rise to an entrapment by estoppel defense"); *see also United States v. Ramirez Valencia*, 202 F.3d 1106, 1109 (9th Cir. 2000) (requiring an affirmative statement by an authorized government official that the defendant's conduct was lawful under federal law).

In his post-hearing submission, Karkalas relies primarily on two asserted government statements to support his entrapment-by-estoppel defense: (1) the statements to the effect that Fioricet was not a controlled substance that Karkalas attributes Andrew Demarest, an attorney representing the Commonwealth of Pennsylvania and the State Board of Medicine; and (2) the DEA's inclusion of Fioricet on the Exempt Prescription Products List. (Doc. No. 437 at 3–4.) With respect to attorney Demarest's purported statements regarding Fioricet's status as a controlled substance, Karkalas cannot show a violation of his federal constitutional right to due process under *Raley* where he claims to have relied on a state official's advice about federal law.

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[20] For the same reason that he cannot base his due process challenge on the statements of his own private attorneys, Karkalas cannot rely on the discussions he had with attorneys representing the manufacturer of Fioricet to support his *Raley* motion. (*See* Doc. No. 437 at 4 ("[Karkalas] even spoke with a lawyer for the manufacturer who confirmed that the Drug Enforcement Administration had provided the manufacturer with documentation that Fioricet was not a controlled substance.").) The purported statements of a lawyer for a private drug manufacturer representing what was communicated to the manufacturer by the DEA is not a sufficient showing of affirmative misconduct by a government official in a direct statement to the defendant that can form the basis of the *Raley* defense.

See United States v. Achter, 52 F.3d 753, 755 (8th Cir. 1995) (providing that a defendant is not "entitled to rely on representations by state or local officials because these officials lacked the authority to bind the federal government to an erroneous interpretation of federal law") (citing *United States v. Brebner*, 951 F.2d 1017, 1026–27 (9th Cir. 1991)); *see also United States v. Perry*, No. 12-CR-50-LRR, 2012 WL 3597210, at *2 (N.D. Iowa Aug. 20, 2012) (citing cases holding that entrapment-by-estoppel defense for a federal prosecution is unavailable where the statements were made by a state or local official).

The inclusion of Fioricet on the Exempt Prescription Products List does not amount to a statement by a government official that Karkalas's conduct was lawful and upon which he could reasonably rely. In *United States v. Benning*, 248 F.3d 772, 775 (8th Cir. 2001), the Eighth Circuit Court of Appeals concluded that the defendant could not succeed on an entrapment by estoppel defense to felon-in-possession charges where no government official expressly informed him that he could legally own a firearm where he claimed to have relied on language in an ATF form to obtain firearms and failed to conduct a reasonable investigation into that language. 248 F.3d at 776. Here as in *Benning*, Karkalas "[a]t most . . . suffered from a lack of explanation rather than an affirmative misleading interpretation of the statute" provided to him by a government official. *Benning*, 248 F.3d at 776.

Karkalas's Motion to Dismiss All Counts Alleging Distribution of Controlled Substances as Violative of Due Process (Doc. No. 353) should be denied.

V. The Government's Motion to Dismiss Certain Counts at Docket Number 395 and Oz's Motion to Dismiss Duplicative Counts at Docket Number 376

Defendant Oz filed a motion seeking dismissal of either counts 61-72 or counts 73-83 on grounds that each group duplicates the other and alleges the same conduct. (Doc. No. 376, Def. Oz's Mot. to Dismiss Multiplicitous Counts.) The government also filed a motion to dismiss

asserting that "[b]ased on a review of the record, the government has concluded that it is in the interests of justice not to pursue Counts 61-72, but rather to continue the prosecution of Counts 73-83, which describe violations of the [Controlled Substances Act]." (Doc. No. 395, Gov't's Mot. to Dismiss Counts 61-72 Pursuant to Fed. R. Crim P. 48(a).) However, the government seeks to preserve paragraphs 1 through 6 of Counts 61-72, which the grand jury incorporated into Counts 72-83. (*Id.* ¶ 6.)

Defendant Oz did not oppose the government's motion. (*Id.* ¶ 8.) At the December 8, 2015 hearing on the motions, counsel for Oz indicated that Oz agrees the motion is moot. Oz introduced the caveat to his agreement that any dismissal of Counts 61-72 must be with prejudice. Counsel for the government agreed that the dismissal of Counts 61-72 should be with prejudice, so long as that dismissal is subject to the government's indication that paragraphs 1 through 6 of Counts 61-72 not be deemed "dismissed" as those paragraphs were incorporated into other Counts in the Indictment.

Based on the government's motion and Oz's non-opposition, and subject to the qualifications counsel for the parties identified at the hearing, this Court recommends that the government's motion (Doc. No. 395) be **GRANTED** and Counts 61-72 be dismissed with prejudice. However, paragraphs 1 through 6 in Counts 61-72, should not be deemed to be subject to this dismissal.

VI. Recommendation

Based on the foregoing, the Court **HEREBY RECOMMENDS** that:

1. Defendant (8) Elias Karkalas's motion to dismiss certain counts for failure to state an offense (Doc. Nos. 340), be **DENIED**

2. Defendant (2) Moran Oz's motion to dismiss certain counts for failure to state an offense (Doc. No. 377) be **DENIED**;

3. Defendant (8) Elias Karkalas's motion to dismiss certain counts as void for vagueness (Doc. No. 339) be **DENIED**;

4. Defendant (9) Prabhakara Rao Tumpati's motion to dismiss certain counts as void for vagueness (Doc. No. 379) be **DENIED**;

5. Defendant (9) Prabhakara Rao Tumpati's motion to dismiss (Doc. No. 380) be **DENIED**;

6. Defendant (3) Babubhai Patel's motion to join (Doc. No. 417) be **DENIED**;

7. Defendant (8) Elias Karkalas's motion to dismiss certain counts for violating due process rights (Doc. No. 353) be **DENIED**;

8. Defendant (2) Moran Oz's motion to dismiss duplicative counts (Doc. No. 376) be **DENIED AS MOOT**; and

9. The Government's motion to dismiss Counts 61-72 (Doc. No. 395) be **GRANTED**, except that paragraphs 1 through 6 of Counts 61-72 should not be deemed "dismissed" as they are incorporated into other Counts that remain in the Indictment.

Date: February 1, 2016

s/ Jeffrey J/ Keyes
JEFFREY J. KEYES
United States Magistrate Judge

NOTICE

Filing Objections: This Report and Recommendation is not an order or judgment of the District Court and is therefore not appealable directly to the Eighth Circuit Court of Appeals.

Under Local Rule 72.2(b)(1), "a party may file and serve specific written objections to a magistrate judge's proposed finding and recommendations within 14 days after being served a

copy" of the Report and Recommendation. A party may respond to those objections within 14 days after being served a copy of the objections. LR 72.2(b)(2). All objections and responses must comply with the word or line limits set for in LR 72.2(c).

Under Advisement Date: This Report and Recommendation will be considered under advisement 14 days from the date of its filing. If timely objections are filed, this Report and Recommendation will be considered under advisement from the earlier of: (1) 14 days after the objections are filed; or (2) from the date a timely response is filed.